EXHIBIT 28

Document Details

Document No: CC-SOP-000017

Document Title: Identifying, Evaluating and Reporting Suspicious Orders

Document State: Effective

Document Version: 1.0

Release Date: 25 Sep 2017 11:21:16 GMT -04:00

Description: The purpose of this SOP is to provide guidance on identifying, reviewing, documenting and reporting Suspicious Orders in compliance with the Controlled Substance Act and 21 CFR 1301.74(b).

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Decision Date : 17 Aug 2017 15:49:29 GMT -04:00
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Owning Departments:
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Cross Ref Departments:

Printed On: 25 Sep 2017 11:35:39 AM GMT -04:00
Printed For: Greco, Adele (coppeya)
Printed By: Greco, Adele (coppeya)
Print Reason: Contingency Copy

PURDUE PHARMA L.P. and ASSOCIATED US COMPANIES
STANDARD OPERATING PROCEDURE

SOP NUM.: CC-SOP-000017
TITLE: IDENTIFYING, EVALUATING AND REPORTING SUSPICIOUS ORDERS

1. PURPOSE

The purpose of this SOP is to provide guidance on identifying, reviewing, documenting, and reporting Suspicious Orders in compliance with the Controlled Substance Act and 21 CFR 1301.74(b).

2. SCOPE

This procedure applies to all customers and customer Orders for schedule II – V controlled substances and List 1 Chemicals.

3. DEFINITIONS

Computer Errors	Purdue Order processing and fulfillment system errors. These include data entry mistakes, coding errors, software malfunctions, and other computer errors or IT failures.
Order	The combined lines for a controlled substance base code and/or strength on a Purchase Order, DEA Form 222, or Purdue order number.
Order of Interest	An Order for a controlled substance or List 1 chemical which is of unusual size, frequency and/or deviates substantially from a normal pattern- 21 CFR 1301.74(b), that is "pended" by the SOM Tool or by other means, for further review.
SOM	Suspicious Order Monitoring (SOM) - "The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of the suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 CFR 1301.74(b)

SOM Tool	A cloud based IT program that uses an algorithm and custom rules/Thresholds to identify and pend Orders of Interest.
Suspicious Order	An Order for a controlled substance or List 1 chemical which is of unusual size, frequency and/or deviates substantially from a normal pattern- 21 CFR 1301.74(b), that is deemed suspicious after review and is reported to the DEA.
Threshold	Monthly maximum quantity in dosage units for each DEA controlled substance base code and/or strength unique to a customer. The monthly Threshold caps the total number of doses that a customer may order for a controlled substance base code in any calendar month.

4. GENERAL

Every customer Order passes through the SOM Tool for scoring/evaluation. Ethics & Compliance must review all pended Orders. All pended Orders are either cleared after review or rejected. All rejected Orders must be reported as suspicious to the DEA registrant's local DEA office.

5. PROCEDURE

I. Order Review

A. Every Order of Interest pended by the SOM Tool, or identified by other means must be evaluated by Ethics & Compliance to determine if it a Suspicious Order. Evaluations may include but are not limited to:

i. Determining why the Order pended or was identified;
ii. Reviewing customer Order history, including 12-month average;
iii. Reviewing customer Threshold;
iv. Checking the customer file for information related to the Order;
v. Inquiring with Customer Service regarding the circumstances of the Order;

vi. Contacting the customer for additional information regarding the Order.

B. Orders of Interest may be identified by one or a combination of the following:

i. Algorithm
ii. Customer Threshold exceeded

C. The resolution of Orders of Interest include the following:

i. The Order is released with justification documented in the SOM Tool. If the customer was contacted for additional information, attach or copy and paste the customer's response in the SOM Tool.

ii. The Order is rejected but not deemed suspicious. This is used for Order entry errors only. The details of the error are vetted and documented in the SOM tool.

iii. The Order is rejected after being deemed suspicious and is reported to the DEA. The reason for the rejection is documented in the SOM Tool. Ethics & Compliance will notify the customer regarding the rejected Order. A copy of the email sent to the DEA will also be saved in the SOM tool.

D. As a rule, Order quantities are not reduced once the Order has been identified as an Order of Interest, and a Purdue employee has contacted the customer. If the customer claims the Order was an error, (i.e. keystroke mistake) the Order must be rejected and the customer can reorder at their discretion. In the case of an error, the rejected Order is not reported to the DEA as suspicious.

II. Reporting Suspicious Orders

A. If an Order is deemed suspicious, it must be reported to the distributing registrant's local DEA office or DEA Headquarters in writing. An email is sent from Ethics & Compliance to Security & Diversion Control with the following information:

i. Name and DEA # of customer;
ii. Order number and date;
iii. Name and quantity of drug in dosage units;
iv. Reason the order is being reported as suspicious;
v. Any other appropriate information the DEA requests.

Security & Diversion Control sends the Suspicious Order information via email to the DEA with a copy to Ethics & Compliance for record keeping.

B. Computer Errors that result in the shipment of Orders that should have been rejected must be reported to the distributing registrant's local DEA office or DEA Headquarters within three (3) business days of discovery. These notifications must include a description of the scope of the error, date the error was corrected, and details of the affected Order(s) that would have been rejected. A copy of the document that reports the computer error to DEA will be saved in the SOM tool.

6. REFERENCES

N/A

7. CHANGE HISTORY

Version	Section	Change
N/A	N/A	N/A – New SOP

8. ATTACHMENTS

N/A